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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,054	05/31/2001	Gunther Berndt	49589	7665
26474	7590	04/06/2004		
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			EXAMINER EASHOO, MARK	
			ART UNIT 1732	PAPER NUMBER

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,054

Applicant(s)

BERNDL ET AL.

Examiner

Mark Eashoo, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US Pat. 6,221,368) in view of Muller (US Pat. 4,303,344).

Regarding claim 1: Breitenbach et al. teaches the basic claimed process for producing solid forms, comprising: mixing during melt extruding and melt extruding a polymeric binder (9:15-23); at least one active pharmaceutical agent (1:64-2:2 and 6:59-7:63); and forming a string (9:56-66). It is noted that hot-cut pelletization extrudes multiple strings from a die wherein the strings are cut at the die face.

Breitenbach et al. further teaches using various extruders, including multi-screw extruders (8:64-9:5). Although Breitenbach et al. does not distinctly teach a planetary roller extruder, Muller teaches using a geared/toothed planetary extruder (see Figs. and 1:40-2:58). Muller and Breitenbach et al. are combinable because they are concerned with a similar technical difficulty, namely, high mixing at short times. At the time of invention a person having ordinary skill in the art would have found it obvious to have used a planetary roller extruder, as taught by Muller, in the process of Breitenbach et al., and would have been motivated to do so because Muller teaches that such extruders mix very intensely in a short times (Muller, 2:3-9 and Breitenbach et al. 8:25-36).

Apparatus limitations are given little patentable weight in method of making claims. *Stalego v. Heymes et al.*, 120 USPQ 473 (CCPA 1959). For apparatus limitations to be entitled to patentable weight in method claims, the recited structural limitations must affect method in manipulative sense and not amount to mere claiming of a use of a particular structure. *Ex Parte Pfeiffer* 135 USPQ 31 (BPAI 1961). In the instant case, the structural limitations comprising planetary extruder appear to a mere use of the recited structure.

Regarding claim 4: Breitenbach et al. further teaches extruding without kneading disks (8:64-9:5).

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Regarding claim 5: Breitenbach et al. does not teach a specific dwell time for the extrusion process. Nonetheless, Newton teaches that such process parameter are known to be optimized (4:2-21). At the time of invention a person having ordinary skill in the art would have found it obvious to have optimized the process parameter (inclusive of dwell time), as taught by Newton, in the process of Breitenbach et al., and would have been motivated to do so in order to optimize energy cost and avoid damaging the active material by over processing.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US Pat. 6,221,368) in view of Muller (US Pat. 4,268,176) and Muller (US Pat. 4,303,344).

Regarding claim 1: Breitenbach et al. teaches the basic claimed process for producing solid forms, comprising: mixing during melt extruding and melt extruding a polymeric binder (9:15-23); at least one active pharmaceutical agent (1:64-2:2 and 6:59-7:63); and forming a string (9:56-66). It is noted that hot-cut pelletization extrudes multiple strings from a die wherein the strings are cut at the die face.

Breitenbach et al. further teaches using various extruders, including multi-screw extruders (8:64-9:5). Although Breitenbach et al. does not distinctly teach a planetary roller extruder, Muller '176 teaches using a geared/toothed planetary extruder (see Figs. and 1:40-2:58). Muller '176 and Breitenbach et al. are combinable because they are concerned with a similar technical difficulty, namely, high mixing at short times. At the time of invention a person having ordinary skill in the art would have found it obvious to have used a planetary roller extruder, as taught by Muller '176, in the process of Breitenbach et al., and would have been motivated to do so because Muller '344 teaches that such extruders mix very intensely in a short times (Muller '344, 2:3-9 and Breitenbach et al. 8:25-36). Muller '344 is provided for the general teaching known in the extrusion art that planetary extruders preform high mixing at short times.

Apparatus limitations are given little patentable weight in method of making claims. *Stalego v. Heymes et al.*, 120 USPQ 473 (CCPA 1959). For apparatus limitations to be entitled to patentable weight in method claims, the recited structural limitations must affect method in manipulative sense and not amount to mere claiming of a use of a particular structure. *Ex Parte Pfeiffer* 135 USPQ 31

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(BPAI 1961). In the instant case, the structural limitations comprising planetary extruder appear to a mere use of the recited structure.

Regarding claims 2-3: Muller teaches a planetary extruder with eight spindles without kneading disks (2:31-33 and Figs. 1-2).

The motivation to use sure extruder is for the same reason as set forth above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wittrock, Brinkmann, Muller '198, Chszaniecki, Hanslik, Brinkmann et al. '967, Spielhoff, and Kaegi et al. all teach various types of geared/toothed planetary extruders.

Response to Arguments

Applicant's arguments filed 08-MAR-2004 with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

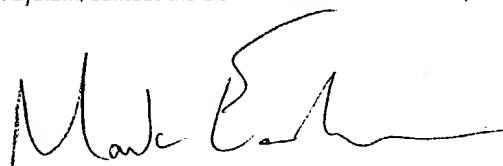
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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Eashoo, Ph.D.
Primary Examiner
Art Unit 1732

30/Mar/04

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30-Mar-04